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November 27, 2023

Honorable Michael A. Shipp, U.S.D.J.
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

Honorable Rukhsanah L. Singh, U.S.M.J.
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

***Re: Johnson & Johnson Talcum Powder Products, Marketing, Sales
Practices and Products Liability Litigation
Case No.: 3:16-md-02738-MAS-RLS***

Dear Judge Shipp and Judge Singh:

We write on behalf of the Plaintiffs' Steering Committee (PSC) in response to the Johnson & Johnson Defendants' (J&J) letter of Tuesday, November 21, 2023.

I. Plaintiffs' Expert Disclosures Were Entirely Consistent with the Court's Scheduling Order

Defendants' objection to the recent filing of Plaintiffs' expert reports is not supported by the language or intent of the Court's October 10, 2023, Scheduling Order. The Order expressly states that "Plaintiffs shall serve, if necessary, supplemental and amended disclosures of all general and case-specific experts pursuant to Rule 26(a)(2)(A) and serve on Defendants' counsel the 26(a)(2)(B) reports of all general and case-specific expert witnesses they may use at trial in any of the Stage Three cases on or before November 15, 2023." Amended disclosures refer to experts previously identified, and supplemental disclosures describe newly identified experts retained during the pendency of the two failed bankruptcies.

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The Order specifically authorizes Plaintiffs to serve amended and supplemental expert reports. As shared with the Court during the September 6, 2023, status conference, at the outset of the litigation, former Chief Judge Freda Wolfson bifurcated the case requiring Plaintiffs to focus first on science and general causation issues. Plaintiffs complied and by the fall of 2021, this MDL was proceeding toward an MDL trial in late spring or early summer of 2022. On July 2, 2021, nearly three years after Plaintiffs' original expert disclosures, Plaintiffs served case-specific expert reports for the six cases in the bellwether pool and for certain general causation experts, amended reports.¹ Thereafter, J&J deposed each of Plaintiffs' experts for which a new or amended report was served. On October 14, 2021, one week prior to the deadline for J&J to disclose the reports of their case-specific experts and ostensibly, general causation experts, J&J embarked on a bankruptcy strategy that resulted in two *LTL* bankruptcies, with each being dismissed. These bad-faith bankruptcies resulted in the needless delay of this litigation for more than **two years**.

Now, J&J wishes to rewind the clock to July 2021 and prevent Plaintiffs from disclosing any new experts or experts with any new opinions. Nothing could be more unfair or unfounded. Time has marched on, and Plaintiffs should have every opportunity to marshal our current understanding of the facts and science in presenting Plaintiffs' case. In keeping with the Court's Order of October 10, 2023, therefore, the PSC served disclosures for experts addressing topics related to general causation, case-specific causation, genetics, asbestos/talc fiber testing, regulatory affairs, and marketing. Doing so does not contradict but is completely consistent with the PSC's statements expressed during the September 6th status conference.

II. Plaintiffs' Service of Amended General Causation Expert Reports Does Not Open the Door for *Daubert* Challenges as to Experts and Opinions Previously Addressed by the Court's April 2020 *Daubert* Order

It is not remarkable that additional scientific literature relevant to Plaintiffs' experts' opinions has been published in the more than two-year interim since the last expert disclosures. The newly published and updated literature was considered by Plaintiffs' experts and incorporated into their amended reports served on November 15, 2023. This updated scientific literature further affirms and strengthens the opinions of the experts that genital exposure of talcum powder can cause ovarian cancer. The methodology employed in the recent reports prepared by the general causation experts is the **same** methodology presented to the Court during the *Daubert* hearings conducted in July 2019 and addressed by the Court in her April 27, 2020, *Daubert* ruling. The concern expressed by Defendants is misplaced. The methodology and opinions of the experts remain unchanged. There is no "rebooting," "do over," "new opinions," or "changed science." (S. Sharko Letter of Nov. 21, 2023, at p. 3 (Dkt. 28727)). Contrary to Defendants' assertions, the

¹ The Johnson & Johnson Defendants suggest that other previously disclosed experts, such as Dr. David Kessler, Dr. Shawn Levy, etc., were not eligible for bellwether trials because they were not "redesignated" on July 2, 2021. This statement is incorrect. Plaintiffs have never withdrawn any expert and all experts for whom *Daubert* motions have been denied are eligible to testify during a bellwether trial or any trial in a remanded case.

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updated scientific literature demonstrates the strength and consistency of the association between genital talcum powder exposure and ovarian cancer.

Counsel for the PSC stand behind the representations made to the Court during the September 6, 2023, status conference. We are prepared to move forward in accordance with the dates set forth in the scheduling order. There is no need for further Rule 702 challenges as to those experts previously admitted by Judge Wolfson to present their general causation and biologic plausibility opinions at trial. The scheduling order entered by the Court anticipated review by experts of additional literature and provides Defendants the opportunity, if deemed appropriate, to conduct limited expert depositions. To be clear, Plaintiffs experts' general causation opinions have not changed, but are further affirmed and strengthened by the updated literature. Further, the methodologies employed have already been approved by the Court.

Because of the passage of time and the extensive number of pleadings that have been filed, Plaintiffs thought it might be helpful for the Court to review the general causation and biologic plausibility experts to whom the Court's *Daubert* order applies. A joint submission by the parties, dated June 11, 2020 (Dkt. 13602, attached as Exhibit A), makes this clear:

- "The parties agree that the Court's rulings on the parties' experts' epidemiology and Bradford-Hill analyses will be binding on all experts who offer opinions in those areas." (p.1)
- "[T]he Court's rulings on the Plaintiffs' Steering Committee's (PSC) experts Dr. Anne McTiernan, Dr. Daniel Clarke-Pearson, and Dr. Arch Carson will be binding on the PSC's other general causation and biologic plausibility experts: Drs. Patricia Moorman, Jack Siemiatycki, Sonal Singh, Rebecca Smith-Bindman, Ellen Blair Smith, Judith Wolf, Sarah Kane, Shawn Levy, Laura Plunkett, and Judith Zelikoff." (p.1, fn 1)

Therefore, for each of these experts, the Court does not need to revisit their general causation or biologic plausibility opinions. In all instances where a new report was served with general opinions (both causation and biologic plausibility), the expert report has merely been updated or supplemented to address newly published scientific literature.

Further, it might also be helpful for the Court to have an explanation of the motions that Judge Wolfson did not rule on but deferred for future consideration. On June 24, 2020 (Dkt. 13715, attached as Exhibit B), the Court deferred ruling on motions related to: 1) the opinions of Plaintiffs' regulatory experts, Dr. David Kessler and Dr. Laura Plunkett; 2) the opinions of Plaintiffs' geology experts, Dr. Robert Cook and Dr. Mark Krekeler; and 3) the opinions of Plaintiffs' Ramon spectroscopy expert, Dr. Alan Campion. Lastly, as a result of the two-year stay due to the bankruptcies, the Court has not addressed the case-specific expert opinions put forth by either party.

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It is this context that the Court must bear in mind when addressing the issues raised in J&J's letter.²

III. Nothing in the Court's Order Prevented Plaintiffs from Disclosing New Witnesses in Support of General Causation – Drs. Rothman, Harlow & Cote

The Court's Order of October 10, 2023, specifically allows for "supplemental reports," such as the reports of Drs. Harlow and Rothman and Dr. Cote who were not previously disclosed as experts in this MDL. Their opinions address general causation issues that have been the subject of this litigation for more than seven years and are very familiar to Defendants. The deadline for J&J's expert reports is not until March 4, 2024. Defendants will have the opportunity to take the deposition of any new experts and further explore their opinions between now and January 22, 2024, the deadline for deposing Plaintiffs' experts. Thus, Defendants claims of prejudice are unsupported and misguided.

Plaintiffs bear the burden of preparing general causation experts not only for the six cases in the bellwether pool but for more than 50,000 cases. Defendants' argument that the newly identified epidemiologic experts are cumulative is premature.

IV. Nothing in the Court's Order Prevented Plaintiffs from Disclosing New Experts on New Subjects

Defendants object to the testimony and report of Dr. George Newman. Dr. Newman is a marketing expert with expertise in the areas of branding and consumer behavior. Defendants argue that Dr. Newman should not be permitted to testify because none of the other experts previously designated addressed marketing. This argument has no basis in fact or law. The complaint is replete with numerous allegations that Defendants through their marketing initiatives misled and deceived consumers for decades that their talcum powder products were safe, pure, and asbestos free. Moreover, the deposition of J&J's 30(b)(6) witness for marketing, which supports Plaintiffs' allegations regarding J&J's deceptive conduct, was completed after the July 2021 expert deadline and less than a month before the first bankruptcy filing. There is simply nothing in the Court's scheduling order, or general fairness, which prevents Plaintiffs from offering an expert in the marketing discipline. Defendants will have ample opportunity to depose and discover Dr. Newman's opinions, file any motion they deem appropriate, and offer their own expert in the area of marketing. Defendants' claim of prejudice is unfounded.

² For a full listing of Plaintiffs' Experts and the status of any previous or pending motions, please see Exhibit C to this letter.

V. Nothing in the Court's Order Prevented Previously Disclosed Experts from Expressing New Opinions

Since July 2021, there have been additional state-court trials in both ovarian cancer and mesothelioma cases, new depositions taken, new documents produced, and new literature published. Further, plaintiffs have advanced their understanding of the evidence that has been amassed to date. Therefore, it should be expected that Plaintiffs' experts have added and refined their opinions. J&J's complaint, while citing no case or court order, is essentially that Plaintiffs' experts must be completely confined to the case as it existed in 2021. But to the contrary, the Court's order contemplated such additional expert opinions. The opinions were properly and timely disclosed. J&J has stated no legal basis for its assertion they are improper.

- **Shawn Levy, PhD.** Defendants object to the addition of case-specific opinions to Dr. Levy's recently disclosed report. Dr. Levy is an expert in genetics. The Court previously denied J&J's motion to exclude his opinions regarding the involvement of genetics in the development of ovarian cancer and specifically, the biologically plausible mechanisms by which talcum powder can cause mutations resulting in ovarian cancer. During the recent state-court trials, J&J has continually made unfounded statements regarding the implications of the results of individual plaintiffs' genetic testing. For that reason, Plaintiffs have put forward Dr. Levy's expert opinions regarding the genetic testing results of the six bellwether pool cases. The Court's order contemplated that reports would be supplemented. The Court has not yet considered case-specific opinions so there is no concern regarding judicial inefficiency.
- **Laura Plunkett, PhD.** Dr. Plunkett is an expert in toxicology and regulatory affairs. The *Daubert* motion regarding Dr. Plunkett's toxicology/biologic plausibility opinions was denied; the previous motion regarding her regulatory opinions was deferred. Since 2018, Dr. Plunkett's expert report has included the regulatory terms, "misbranded" (i.e., false labeling) and "adulterated" (i.e., product poses a risk to human health). Likewise, Dr. Plunkett's reports have stated that talcum powder contains asbestos, fibrous talc, and other carcinogens since 2018. Her report added language stating that "failure to list those talc constituents [asbestos, fibrous talc, nickel, chromium, and cobalt] on its labeling would be consistent with the FDA's definition of a misbranded product as well as an adulterated product." The statement merely refines the language setting out her opinions, rather than adds to them.
- **David Kessler, MD, JD.** Dr. Kessler is a former Commissioner of the United States Food and Drug Administration and an expert in regulatory affairs. Dr. Kessler was not deposed in relation to his November 2018 report, and a decision on the previously filed motion regarding Dr. Kessler's regulatory opinions was deferred. J&J's statement that

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Dr. Kessler was not previously identified for bellwether trials is incorrect. All general experts identified in November 2018 have always been in play for the bellwether trials. Plaintiffs have not withdrawn any experts. Plaintiffs simply chose not to supplement Dr. Kessler's report in 2021 since at that time, he was serving as Chief Science Officer of the United States Covid-19 Response. Dr. Kessler is currently a Professor of Pediatrics, Epidemiology and Biostatistics at the University of California, San Francisco and is able to testify. In light of the many additional depositions that have been taken since 2018 and other newly discovered evidence, Dr. Kessler updated his report accordingly.

- **William Longo, PhD and Mark Rigler, PhD.** The Court's *Daubert* order provided that Drs. Longo and Rigler may testify to their TEM (transmission electron microscopy) results identifying *amphibole asbestos and fibrous talc*. Plaintiffs anticipate Dr. Longo or Dr. Rigler offering such opinions at a bellwether trial or the trial of future remanded cases. Drs. Longo and/or Rigler's newly disclosed reports outline additional results of testing Johnson's Baby Powder and Shower to Shower for not only amphibole asbestos and fibrous talc, but also for chrysotile asbestos. These opinions were not previously disclosed in the MDL and were not addressed by the *Daubert* order. The *Daubert* order stated that, "By failing to conduct an exposure analysis, Dr. Longo's opinion on the likelihood that talc users were exposed to a 'significant' amount of asbestos . . . is too attenuated from his findings." (*Daubert* Order Opinion at p.59). At that point, no potential bellwether plaintiffs had been identified. Therefore, Dr. Longo was unable to conduct any exposure analyses. That is no longer the case. Dr. Longo has reviewed detailed usage information for each of the six bellwether pool plaintiffs and conducted a case-specific exposure analysis. As J&J is well aware, this analysis is completely different than the statement the Court referenced. These are new case-specific opinions. The Court has not yet considered case-specific opinions so there is no concern regarding judicial inefficiency.

Thank you for your consideration of these matters. We believe a status conference would be helpful to the parties and the Court, and Plaintiffs look forward to discussing these matters with the Court in more detail at that time.

Respectfully submitted,

/s/ P. Leigh O'Dell

P. Leigh O'Dell

/s/ Michelle A. Parfitt

Michelle A. Parfitt

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cc: Hon. Joel Schneider, U.S.M.J. (ret.) (via email)
Susan Sharko, Esq. (via email)
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